DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-539/S-002

Cumberland Pharmaceuticals, Inc.
Attention: Amy Rock, Ph.D.
Regulatory Affairs
209 10th Avenue South, Suite 332
Nashville, Tennessee 37203

Dear Dr. Rock:

Please refer to your supplemental new drug application dated February 18, 2004 (received February 19, 2004), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Acetadote® (acetylcysteine) Injection.

This supplemental new drug application provides for a revised package insert based upon guidelines used to dose pediatric patients in Australia, and guidelines used in observational studies submitted as part of the original NDA.

We acknowledge receipt of your submission dated March 08, 2004.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please submit final printed labeling (FPL) identical to the enclosed labeling text for the package insert, submitted February 18, 2004. In addition, the final printed labeling shall contain the approved revisions to the labeling text for the package insert of supplemental NDA 21-539/S-001, approved April 28, 2004. These revisions are terms of the approval of this application.

You may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-539/S-002". Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul E. Levine, Jr., R.Ph., J.D., Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

Appendix A
Revised Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Justice

4/28/04 10:51:49 AM